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Theory and Practice of Compounding Otic Preparations

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1.5 Credit Hours (0.15 CEUs)

Goals: The goals of this article are to provide basic information on the anatomy, physiology and common disorders of the ear and discuss examples of compounded drugs and dosage forms used in their treatment.

Objectives: After reading and studying the article, the reader will be able to:

1. Describe the anatomy and physiology of the ear.
2. Exhibit an understanding of common otic disorders.
3. List common drugs and their dosage forms used in treating otic disorders.
4. Exhibit an understanding of the physicochemical considerations in developing otic preparations.
5. Counsel a patient on the proper use of otic preparations.

Introduction

Otic disorders are usually treated with medications applied locally. Administration of medications to the ear involves placing a liquid in the ear and inserting a cotton plug to keep the medication from draining out. Ear irrigants are another common class of otic preparations that are used to clean debris from the ear.

Otic (aural) preparations may consist of solutions, suspensions, ointments, gels, and powders. Liquid ear preparations are usually placed in the ear canal drop-wise for the removal of excessive cerumen (ear wax) or for the treatment of ear infections, inflammation, or pain. Since the outer ear is a skin-covered structure, skin conditions which arise are treated using a variety of topical dermatological preparations.

Anatomy and Physiology of the Ear

The external ear is made up of the pinna (auricle) and the external auditory canal. Terminating the end of the external auditory canal is the tympanic membrane, which forms the beginning of the middle ear. The auricle consists of a thin layer of highly vascular skin firmly attached to cartilage. There is generally no fatty tissue or subcutaneous tissue in the auricle, except for the ear lobe, which is composed primarily of fatty tissue with fewer blood vessels than the rest of the auricle.

Starting from the exterior and moving along into the external auditory canal, the first one-third to one-half is the outer cartilaginous portion, followed by the inner body or osseous portion. The end of the ear canal ends in a cul-de-sac. The external auditory canal of adults tends to be “S” shaped and that of children tends to be shorter and straighter.

The auricle is susceptible to bleeding when scratched because it is more rigid and lacks the flexibility normally provided by a subcutaneous layer of fat. The auricle area contains many nerves which can cause enhanced pain sensations when inflamed. Moving further into the external auditory canal, the skin becomes thicker and contains both apocrine and exocrine glands along with hair follicles. The skin lining the external auditory canal is continuous with that forming the tympanic membrane outer layer.

Cerumen is produced as a part of the body’s normal defense mechanisms. Cerumen is formed when the oily secretions from the exocrine gland mixes with the milky, fatty fluid from the apocrine glands. The cerumen serves to lubricate the canal and entrap dust and foreign materials; it also provides a waxy, water-proof

barrier to the entry of pathogens. Under normal conditions, bacterial growth is inhibited because the cerumen contains lysozymes and has an acidic pH. Normal skin growth results in a continuous shedding of the external layer, including the skin in the ear canal. The shed skin cells are continuously mixed with the cerumen. This mixture normally moves outward to the external opening of the ear when the jaw moves, such as while talking or chewing. The ear canal is usually self-cleaning. The cerumen may progress from an oily and paste-like appearance to that of being dry and flaky. The color ranges from light gray to orange or brown and may darken upon exposure to air.

Common Otic Disorders

Under certain circumstances, such as when moisture accumulates, the external auditory canal can form a dark, moist, warm environment that is ideal for bacterial growth. The protective layer of the skin can be challenged and traumatized by fingernails, cotton-tipped swabs, hair pins or any other object inserted into the ear in attempts to clean it. Once the integrity of the skin is penetrated, pathogenic organisms can enter and initiate an infection. Other injuries can result from burns, sporting accidents, ear piercing and improperly fitted ear molds or hearing aids. Ear complaints affect patients of all ages and range from simple, including excessive ear wax, to more complex disorders, including very painful ear infections.

Impacted Cerumen

Ear wax impaction may be experienced by up to about 6 percent of the general population; this is one of the most common ear problems presented to physicians. Some individuals are more prone to impacted cerumen, especially those with narrow or mis-shaped ear canals and those with excessive hair growth in the canal. Others with a greater than average tendency for impacted cerumen are those with overactive glands, those wearing hearing aids, as well as those using ear plugs to prevent water from entering the ear and to muffle loud noises. If cerumen is prevented from its natural migration outward to the opening of the ear canal, it may build up and dry out, forming a plug. As cerumen becomes dry, it is more difficult to remove from the ear. Impacted cerumen buildup is experienced by the patient as a sense of fullness or pressure within the ear, sometimes associated with a dull pain.

It is obvious from this discussion that any object placed in the ear may tend to compress the cerumen and alter its normal outward flow within the ear. In fact, cotton-tipped swabs can result in pushing the cerumen back deeper into the ear.

There are a number of methods of breaking up the cerumen and aiding its removal from the ear, including preparations containing hydrogen peroxide, glycerin, carbamide peroxide and olive oil. The carbamide peroxide and hydrogen peroxide create a mechanical "bubbling" action that can serve to soften and break up dried cerumen and move the pieces of ear wax toward the outer portion of the ear canal; they also have anti-infective properties. Glycerin is hygroscopic and can absorb moisture from the environment and soften the cerumen. The olive oil partially dissolves the cerumen and acts as a softening agent, allowing its easy removal. These liquids are viscous and will tend to stay within the ear canal if a small piece of cotton is placed at the entrance to the ear.

Water-Clogged Ears

If cerumen builds up in an ear and the ear is exposed to water, as when one takes a shower or swims, water may get behind the cerumen in contact with the tympanic membrane. The presence of this moisture may result in maceration of the skin lining the ear and the tympanic membrane, contributing to inflammation and infection of the external auditory canal, a condition known as swimmer's ear. This situation can also result from excessive sweating in humid environments, as well as from the improper use of aqueous products to clean the ear.

Symptoms of water-clogged ears include a feeling of fullness and wetness of the ear; this may be accompanied by some gradual loss of hearing. As the condition progresses, it can result in tissue maceration, leading to itching, pain, inflammation and/or infection.

Preparations used to treat water-clogged ears include iso-propyl alcohol, glycerin, boric acid, hydrocortisone, ethyl alcohol and acetic acid. Infections can also be treated with otic drops containing a mixture of aminoglycoside antibiotics and anti-inflammatory corticosteroids in an acidic vehicle (neomycin sulfate, polymyxin B sulfate and hydrocortisone). The alcohols aid in reducing surface tension and mix with the water, thus facilitating its removal through the ear canal. The glycerin also aids in absorbing the water. Acetic acid reduces the pH in the ear canal which minimizes bacterial growth. Hydrocortisone assists in reducing inflammation, and the antibiotics help reduce infection.

Disorders of the Skin in the Ear

Disorders of the skin in the ear can include contact dermatitis, seborrhea, psoriasis and boils. Contact

dermatitis may result from either an allergy or an irritant and may present as maculopapular rash and vesicles. The rash may be associated with pruritis, erythema and edema. Mild irritants such as soaps and detergents can cause an inflammatory response similar to allergic contact dermatitis. Contact dermatitis can be treated with a 2.5 percent aluminum acetate solution that has antipruritic, anti-inflammatory and some antibacterial properties. This astringent precipitates proteins and dries the affected area. It can also reduce the pH of the area, which can inhibit bacterial and fungal growth.

Seborrhea affecting the ear presents with visible drying and flaking of the skin, with or without fissuring of the skin. The associated itching can be treated with topical hydrocortisone-containing preparations.

Psoriatic lesions present as thickened, erythematous, silvery scales that occur most frequently on the knees, elbows, torso and scalp, including the ear. These can be treated with routine medications used to treat psoriasis, as well as hydrocortisone-containing preparations for the discomfort.

Localized infections of hair follicles can result in boils or furuncles. The causative organism often is a Staphylococcus species. The boil generally begins as a red papule and develops into a superficial pustule with a core of pus and a reddened area around the base. The lesion slowly enlarges and becomes firm before softening and opening in a couple of weeks, discharging its contents. Pain can be caused by the swelling and the tight skin. Generally, boils are self-limiting. Treatment can include warm compresses and topical antibiotics.

In the event of excessively dry skin in the ear canal, mineral oil or olive oil may help counteract dryness and repel moisture.

Ear Pain

Pain in the ear frequently accompanies ear infection or inflamed or swollen ear tissue. The pain is often out of proportion to the actual condition. Because the ear canal is so narrow, even a slight inflammation can cause intense pain and discomfort for the patient. Topical analgesic agents are generally employed together with internally administered analgesics, such as aspirin, and other agents, such as anti-infectives to combat the cause of the problem.

Topical analgesics for the ear are usually solutions and frequently contain the analgesic antipyrine and the local anesthetic benzocaine in a vehicle of propylene glycol or anhydrous glycerin. The hygroscopic vehicles reduce the swelling of tissues by drawing water out of the inflamed sites and into the vehicle. This in turn helps to relieve pain associated with the swelling. These vehicles similarly deprive microorganisms of moisture, thus decreasing microbial growth. These preparations are commonly employed to relieve the symptoms of acute otitis media.

Drugs used in treating otic disorders

Categories of medications commonly used in the ear include local anesthetics, cleansing agents (peroxides), anti-infectives, and antifungals. Also included are liquids for cleaning and/or drying out the external ear and for removing any fluids that may be entrapped by a local waxy buildup.

Anti-infective agents include drugs such as chloramphenicol, ciprofloxacin, colistin sulfate, gentamicin sulfate, neomycin and polymyxin B sulfate. For fungal infections, nystatin, ketoconazole, amphotericin and clotrimazole are used. These agents are formulated into ear drops (solutions or suspensions) in a vehicle of anhydrous glycerin or propylene glycol. These viscous vehicles permit maximum contact time between the medication and the tissues of the ear. In addition, their hygroscopicity causes them to draw moisture from the tissues thereby reducing inflammation and diminishing the moisture available for the life process of the microorganisms present. To assist in relieving the pain which frequently accompanies ear infections, a number of anti-infective otic preparations also contain analgesic agents such as antipyrine and local anesthetics such as lidocaine, dibucaine, and benzocaine.

Dosage forms used in treating otic disorders

Otic preparations can be in liquid, ointment, gel or powder dosage forms. The liquid dosage forms, i.e. otic solutions and suspension, are intended to be instilled into the ear. Solutions are also used for irrigating the ear. Otic irrigating solutions may consist of surfactants, weak sodium bicarbonate, boric acid (0.5 - 1 percent), or aluminum acetate solutions. These solutions may be warmed to 37^0C before instillation into the ear. These irrigating solutions may be used to remove ear wax, purulent discharges of infection, and foreign bodies from the ear canal.

Otic suspensions can be used when sustained drug action is desired, or when the drug is not soluble in the vehicles commonly used in otic preparations. Pharmacists should be aware that there may be substantial differences in the formulation of some otic suspensions that could be potentially bothersome to the patient. This is particularly true with regard to the inactive or inert ingredient differences between formu-

FORMULATIONS FOR TREATING OTIC DISORDERS

Removal of cerumen

Urea and Hydrogen Peroxide Otic Solution

Rx Carbamide Urea	6.5 g
Glycerin, qs	100 mL

Dissolve the carbamide urea in sufficient glycerin to volume, package and label. A beyond-use date of up to six months can be used for this preparation.

Treatment of water-clogged ears

Boric Acid 2 percent in Isopropyl Alcohol

Rx Boric Acid	2 g
Isopropyl alcohol 70 percent, qs	100 mL

Dissolve the boric acid in sufficient isopropyl alcohol 70 percent to volume, package and label. A beyond-use date of up to six months can be used for this preparation.

Skin disorders of the ear

1. Aluminum Acetate Otic Solution

Rx Aluminum subacetate topical solution	54.4 mL
Glacial acetic acid	1.5 mL
Purified water, qs	100 mL

Slowly, and with stirring, add the glacial acetic acid to the aluminum subacetate topical solution. Add sufficient purified water to volume and mix well. Package and label. A beyond-use date of up to six months can be used for this preparation.

2. Hydrocortisone and Acetic Acid Otic Solution

Rx Hydrocortisone	1 g
Glacial acetic acid	2 mL
Propylene glycol, qs	100 mL

Add the hydrocortisone and glacial acetic acid to sufficient propylene glycol to volume and mix well. The hydrocortisone will slowly dissolve. Gentle heat can be used if required. Package and label. A beyond-use date of up to six months can be used for this preparation.

3. Acetic Acid and Glycerin Otic Solution

Rx Glacial acetic acid	0.5 mL
Glycerin	20 mL
Purified water, qs	100 mL

Mix the glacial acetic acid and glycerin. Add sufficient purified water to volume and mix well. Package and label. A beyond-use date of up to six months can be used for this preparation.

4. Ciprofloxacin 1 percent Otic Drops

Rx Ciprofloxacin	1 g
Propylene glycol	50 mL
Glycerin, qs	100 mL

Pulverize sufficient ciprofloxacin tablets to a very fine powder (or use ciprofloxacin hydrochloride USP monohydrate powder). Add the propylene glycol slowly and mix well. Add sufficient glycerin to volume and mix well. Package and label. A beyond-use date of up to six months can be used for this preparation.

5. Gentamicin Sulfate 0.1 percent Otic Solution

Rx Gentamicin sulfate	100 mg (equivalent activity)
Glycerin, qs	100 mL

Add the gentamicin sulfate to sufficient glycerin to volume and mix well. Package and label. A beyond-use date of up to six months can be used for this preparation.

6. Nystatin 100,000 units/mL Otic Suspension

Rx Nystatin	10,000,000 units
Propylene glycol	25 mL
Glycerin, qs	100 mL

Add the nystatin to the propylene glycol and mix well. Add sufficient glycerin to volume and mix well. Package and label. A beyond-use date of up to six months can be used for this preparation.

7. Neomycin Sulfate, Polymyxin B Sulfate, Triamcinolone and Nystatin Otic Suspension

Rx Neomycin Sulfate	350 mg
Polymyxin B Sulfate	1,000,000 units
Triamcinolone	100 mg
Nystatin	10,000,000 units
Propylene glycol, qs	100 mL

Blend the powders with sufficient propylene glycol to volume and mix well. Package and label. A beyond-use date of up to 30 days can be used for this preparation.

8. Clotrimazole and Gentamicin Sulfate Otic Liquid

Rx Clotrimazole	1 g
Gentamicin sulfate	300 mg
Propylene glycol 300, qs	100 mL

Add the clotrimazole and gentamicin sulfate to sufficient polyethylene glycol 300 to volume and mix well. Low heat can be used if needed to effect solution. Package and label. A beyond-use date of up to six months can be used for this preparation.

9. Triamcinolone 0.1 percent Otic Solution

Rx Triamcinolone	100 mg
Propylene glycol	50 mL
Glycerin, qs	100 mL

Add the triamcinolone to the propylene glycol. Add sufficient glycerin to volume and mix well. Package and label. A beyond-use date of up to six months can be used for this preparation.

Treatment of Ear Pain

lations from various manufacturers which are considered equivalent on the basis of the active ingredient (s) and strength. For example, several suspension combinations of polymyxin B sulfate, neomycin sulfate and hydrocortisone have been shown to be more acidic, i.e., pH 3.0 to 3.5, compared to some commercial products which posses a higher pH in the range of 4.8 to 5.1. Consequently, there is a risk that a burning, stinging sensation can occur when the drops are introduced into the ear of young children, especially

1. Lidocaine Hydrochloride 0.5 percent Otic Solution

Rx Lidocaine Hydrochloride	500 mg
Glycerin	50 mL
Propylene glycol, qs	100 mL

Add the lidocaine hydrochloride to the glycerin and sufficient propylene glycol to volume and mix well. Package and label. A beyond-use date of up to six months can be used for this preparation.

2. Tetracaine 30 percent Otic Solution

Rx Tetracaine	30 g
Propylene glycol, qs	100 mL

Add the tetracaine to sufficient propylene glycol to volume and mix well. Package and label. A beyond-use date of up to 30 days can be used for this preparation.

3. Antipyrine and Benzocaine Otic Solution

Rx Antipyrine	810 mg
Benzocaine	210 mg
Glycerin, qs	15 mL

Add the antipyrine and benzocaine to sufficient glycerin to volume, mix well and allow to sit until all dissolved. Package and label. A beyond-use date of up to six months can be used for this preparation.

Note: As an option, 0.25 percent phenylephrine hydrochloride can be added to this preparation. A beyond-use date of only 14 days can be used for this modified formulation, when stored in the refrigerator.

those with tympanostomies.

Otic ointments and gels are semisolid preparations that are applied to the exterior of the ear. Any ointment base can be used in their preparation. They may include antibacterial, antifungal, or corticosteroid ingredients.

Insufflations are preparations made of finely divided powders that are administered to the ear canal. Insufflating a powder into the ear canal is not too common because the ear lacks fluids and a powder-wax buildup may occur. Fine powders used as insufflations may contain an antibacterial and/or an antifungal that will create a repository for the drug. A small rubber or plastic bulb insufflator (powder blower, puffer) can be used to blow, or insufflate, the powder into the ear.

Physicochemical Considerations

Physicochemical considerations in developing otic preparations include solubility, viscosity, tonicity, surfactant properties and inclusion of preservatives. Although sterility is not generally a consideration, the products need to be “clean.”

Many drugs are soluble in the vehicles commonly used in these preparations. If a drug is insoluble in these vehicles, the preparation can be formulated as a suspension. Since most of these vehicles are relatively viscous agents, the addition of suspending agents may not be necessary. The viscosity of the preparation is important in keeping the medication in the ear canal. If the preparation is too thin, the medication will drain out of the ear. On the other hand, if the medication is too thick, it may not reach the inner recesses of the ear.

Tonicity and hygroscopicity are important in the product’s ability to aid in withdrawing fluids from the immediate area of the ear. If the product is hypertonic, some fluid may be withdrawn from the ear, thereby releasing some of the pressure. If the product is hypotonic, however, some fluid may flow into the area.

Because many ear conditions are related to the difficulty in cleaning the ear, the presence of a surfactant in the preparation helps the medication diffuse throughout the ear, and aids in emulsifying and breaking up ear wax. This action makes it easier to remove any foreign material.

Many otic preparations are self-preserving because of the high concentration of solvents such as glycerin and propylene glycol. If these agents are not present, it may be wise to add a preservative to minimize the chance of introducing bacteria that might grow in an unpreserved product. As determined on an individual product basis, some liquid otic preparations require preservation against microbial growth. When preservation is required, agents such as chlorobutanol (0.5 percent), thimerosal (0.01 percent), and combinations of the parabens are commonly used. Antioxidants, such as sodium bisulfite, and other stabilizers are also included in otic formulations, as required. Ear preparations are usually packaged in small (5 to 15 mL) glass or plastic containers with a dropper.

Vehicles

Vehicles used most often in otic preparations are glycerin, propylene glycol and the lower molecular weight polyethylene glycols (PEGs), especially PEG 300. These vehicles are viscous and will adhere to the ear canal. Water and alcohol (ethanol and isopropyl) can be used as vehicles and solvents for some medications; however, they are used primarily for irrigation, since one of the therapeutic aims of these preparations is to keep the ear canal dry to minimize bacterial/fungal growth. Alcohol can be used full strength. Vegetable oils, especially olive oil, are also good vehicles. Mineral oil has been used as a vehicle

for some antibiotics and anti-inflammatory medications. Otic ointments primarily contain petrolatum as a vehicle, whereas otic powders may contain talc or lactose as a vehicle.

Quality Control

The compounding pharmacist should follow standard quality control procedures. These include checking the volume/weight, pH, viscosity, appearance, and odor of these products.

Packaging, Storage and Labeling

Otic preparations should be packaged in dropper containers, puffers, syringes (without needles) or tubes as deemed appropriate for the product and method of administration. Generally, otic preparations should be stored at either room or refrigerated temperatures. They should not be frozen. These preparations should be labeled "For the Ear", "Discard after [appropriate date]", and "Use only as directed" and "Keep Out of Reach of Children."

Stability and Beyond-Use Dates for Otic Preparations

The following beyond-use recommendations can be exceeded if there is valid scientific information to support the stability of the product.

Beyond-use dates for water-containing formulations are no later than 14 days, when stored at cold temperatures, for products prepared from ingredients in solid form. If nonaqueous liquids are prepared using a manufactured product, the beyond-use recommendation is no later than 25 percent of the time remaining on the product's expiration date or 6 months, whichever is earlier, and 6 months if prepared from ingredients with a USP-NF monograph. For all other products, the beyond-use recommendation is the intended duration of therapy or 30 days, whichever is earlier.

Proper administration and use of otic drops

Patients should be instructed on how to apply drops to the ear from dropper bottles. They should also be told to place a cotton or gauze pad in the ear to keep the liquid from escaping.

When ear drops are prescribed, it is important for the pharmacist to first determine how the drops are to be used. For example, ear wax removal drops should be instilled and then removed by the patient with an ear syringe. Alternatively, drops intended to treat external otitis infection are intended to be instilled and left in the ear.

The pharmacist should make sure the patient or the parent understands that administration is intended for the ear and its frequency of application. To facilitate patient acceptance, the pharmacist should point out that the bottle or container of medication should first be warmed in the hands, and if the product is a suspension, shaken well prior to withdrawal into the dropper. The pharmacist should also explain the need to store the medication in a safe place out of the reach of children and away from extremes of temperature.

When instilled into the ear, the ear lob should be held up and back in order to allow the drops to run in deeper. For a child, the ear lobe should be held down and back. For convenience it is probably easier to have someone other than the patient administer the drops.

Some ear drops by virtue of their formulation, i.e., low pH, may cause stinging upon administration. Parents and children should be forewarned, especially if a child has tympanostomy tubes in the ear for example. The patient should also be made to understand the length of time in days that the medication is intended to be used. For antibiotic ear drops, it is not necessary to finish the entire bottle because therapy could last 20 to 30 days, depending upon the dosage regimen. Therefore, patients should be instructed to continue using the drops for 3 days beyond the time ear symptoms disappear. Products for swimmer's ear or otitis externa may take up to 7 to 10 days to demonstrate efficacy.

If a child is prone to developing ear infections as a result of swimming or showering, it might be advisable to recommend that the parents consult a physician for prophylactic medication to use during swimming season, and consider using form-fitting ear plugs that fit snugly in the ear when swimming and showering. Further, after the child emerges from the water or shower, the parents can be advised to use a hair dryer on a low setting to dry out the ear. The dryer should not be positioned too close to the child's ear.

Suggested Readings

1. 'A practical guide to contemporary pharmacy practice' by Judith E. Thompson, Third Edition. Lippincott, Williams & Wilkins. 2009
2. 'Pharmaceutical Dosage Forms and Drug Delivery Systems' by Howard C. Ansel, Nicholas G. Popovich, and Loyd V. Allen, Jr. Ninth Edition. Lippincott, Williams & Wilkins. 2011.

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1. Common Otic Disorders include:

A. Impacted cerumen
B. Water-clogged ears
C. Disorders of the skin in the ear
D. All of the above

2. Physicochemical considerations in developing otic preparations include all of the following, EXCEPT:

A. Solubility
B. Sterility
C. Viscosity
D. Surfactant properties

3. Vehicles used most often in otic preparations include all the following, EXCEPT:

A. Glycerin
B. Propylene glycol
C. Simple Syrup
D. Polyethylene glycol 300

4. Which of the following is NOT an antimicrobial preservative used in otic products?

A. Chlorobutanol
B. Methyl and propyl paraben
C. Thimerosal
D. Polysorbate 80

5. Water-clogged ears can be treated with preparations containing the following, EXCEPT:

A. Glycerin
B. Iso-propyl alcohol
C. Acetic acid
D. Water

6. Which of the following statements concerning the benefits of using glycerin in otic preparations is FALSE?

A. Glycerin draws moisture out of inflamed sites.
B. Glycerin deprives microorganisms of moisture.
C. Glycerin imparts a sweet taste.
D. Glycerin itself has antimicrobial properties making the otic preparation self-preserving.

7. Drugs used to relieve pain in the ear include all of the following, EXCEPT:

A. Antipyrine
B. Benzocaine
C. Lidocaine Hydrochloride
D. Ethyl alcohol

8. Identify the FALSE statement about otic preparations from the following:

A. Olive oil should not be used in otic preparations.
B. Acetic acid reduces the pH in the ear canal which minimizes bacterial growth.
C. Hydrocortisone can be used to reduce inflammation.
D. Aminoglycoside antibiotics such as neomycin sulfate can be used to combat infections in the ear.

9. Otic preparations should be labeled with the following, EXCEPT:

A. “Apply medication using a cotton-tipped swab inserted into the ear”
B. “For the Ear”
C. “Use only as directed”
D. “Keep Out of Reach of Children”

10. Typical anti-fungals used to treat otic infections include all of the following, EXCEPT:

A. Nystatin
B. Sodium bisulfite
C. Ketoconazole
D. Amphotericin

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Is relevant to my practice	___Yes	___No			

I hereby certify that I completed this self-study program independently and without assistance from any other party.

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